

## **REMARKS**

This paper is intended as a full and complete reply to the Office Action dated January 20, 2010, having a shortened statutory period set to expire on April 20, 2010.

Claims 1-4, 6-10 and 22-24 are pending in the application.

Claims 1-4, 6-9 and 22-24 are currently amended in this response.

Claims 5 and 11-21 have been cancelled.

Applicant's method is specifically adapted for tracking controlled substances, preventing abuse, and managing prescription information in the aggregate, through use of an independent clearinghouse-type of prescriptive information. Continuously updatable information from both affiliated and non-affiliated parties is thereby accessible, in real time, and in context. An unbiased method is thereby provided which prevents prescriptive drug abuse, medical complications and death, and saves billions of dollars in healthcare costs and related costs to third party providers, insurers and governmental programs.

### **Claim Rejections – 35 USC §112**

Applicants appreciate the withdrawal of the rejection of claims 1-4, 6-10 and 22-24 under 35 USC 112, second paragraph, due to the amendment filed October 30, 2009.

### **Claim Rejections – 35 USC §101**

Applicants appreciate the withdrawal of the rejection of claims 1-4, 6-10 and 22-24 under 35 USC 101, due to the amendment filed October 30, 2009.

### **Claims Rejections – 35 USC §103**

Claims 1-4, 6-10 and 22 were rejected under 35 USC § 103(a) as being unpatentable over Cunningham (US 6,859,708) in view of Denny (US 6,687,676). Cunningham was cited to identify all elements of the claims, except Cunningham does not expressly disclose unaffiliated pharmacies, nor does Cunningham disclose a complete prescription history comprising all prescription medications purchased in the aggregate by said selected prescription purchaser from all of said plurality of affiliated and

unaffiliated pharmacies, and further Cunningham does not disclose generating from said complete prescription history of said selected purchaser one or more patterns defined by the pharmaceutical data associated with the selected purchaser which patterns empower the identification of prescriptive drug abuse and the control thereof. However, it was stated in the Office Action that Denny discloses unaffiliated pharmacies and that a complete prescription history is provided in Denny. Thus, it was postulated that it would have been obvious to a person of ordinary skill in the art to include the aforementioned features of Denny within Cunningham. The motivation for doing so would have been to provide centralized information in order to prevent improper use of prescribed drugs and fraud.

Further, Claims 23 and 24 were rejected under 35 USC 103(a) as being unpatentable over Cunningham (US 6,859,780) in view of Denny (US 6,687,676) and further in view of Edelson et al. (US 5,737,539). Cunningham and Denny were cited as not expressly disclosing one or more patterns from the prescription history to indicate prescription duplication, multi-source prescription abuse, or combinations thereof. Edelson was cited as disclosing one or more patterns from the prescription history indicating prescription duplication, multi-source prescription abuse or combinations thereof. Thus, at the time of the invention, it was believed to have been obvious to a person of ordinary skill in the art to combine the aforementioned feature of Edelson with Cunningham and Denny. The motivation for doing so would have been to control abuse by refusing to process the prescription.

The analysis to determine whether the claimed invention meets the statutory conditions for patentability under 35 U.S.C. §103 requires that “obviousness,” which is a legal term of art, be evaluated in each individual situation. More specifically, under *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966), obviousness must be determined based upon the following considerations:

The scope and content of the prior art;

The differences between the subject matter sought to be patented and the prior art;

The time at which the invention was made;

The level of skill of a person having ordinary skill in the art to which the invention pertains; and

Objective evidence indicating obviousness or nonobviousness, i.e. evaluating whether the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art.

Claim 1 recites a method usable to track prescriptive medication and control drug abuse that includes providing computer connections to entities including both affiliated and unaffiliated pharmacies, obtaining and storing pharmaceutical data related to prescriptive medication purchases by a plurality of purchasers from both the affiliated and unaffiliated pharmacies, and selectively transferring the pharmaceutical data to at least one of the entities to obtain a complete prescriptive history for a selected purchaser. Claim 1 combines and utilizes data from the entities/pharmacies that are affiliated with one another (i.e., two locations within a pharmacy or hospital chain), as well as pharmacies/hospitals that are unaffiliated with one another. (Applicant's Specification, Paragraph [0061]). The prescriptive history is based on all medications purchased in the aggregate, by a selected purchaser, from all of the affiliated and unaffiliated pharmacies from the time the connection was made. The complete prescriptive history is then used to generate patterns that flag prescriptive drug abuse, such as prescription duplication, multi-source prescription abuse, and similar patterns. (Applicant's Specification, Paragraph [0070])

The cited references, Cunningham in view of Denny, neither alone, nor in combination, teach each element of the claimed invention.

Cunningham describes a system used to track product media, i.e. tracking a clinical trial and/or sample pharmaceutical products; but does not teach a system adapted for preventing prescriptive drug abuse. Cunningham discusses that prescribers are given encoded media, such as a magnetic card, which are activated by the prescriber through connection to a central computing station before distribution to a patient, who then exchanges the activated media at a pharmacy for corresponding products. (Cunningham, Column 2, Line 64 – Column 3, Line 34). After activation of the media, and after validation of the media and dispensation of product, a database records the transactions,

enabling audit and accounting procedures, which facilitates replenishment of dispensed products and payment of fees. (Cunningham, Column 3, Lines 40-53).

Cunningham defines the level of skill of a person having ordinary skill in the art to which the claimed invention pertains, and clearly teaches away from the claimed invention. Cunningham is silent concerning the primary function of the claimed invention, namely, Cunningham does not provide a prescription history for preventing prescription drug abuse. Cunningham further teaches away from the claimed invention by specifically being adapted to be applicable to only a small, selected number of prescription drug users, namely, those involved in product or clinical trials for testing a drug's efficacy. (See, e.g., Cunningham, Figures 1-4 and 6). The claimed invention, conversely, provides a complete prescriptive history for preventing prescription drug abuse.

Edelson describes an electronic prescription creation system, which accesses remote databases to obtain formulary and patient history information. (Edelson, Abstract) A patient condition or problem is associated with each drug prescribed to memorialize a physician's intent and treatment objectives. (Edelson, Column 4, Lines 43-45).

Edelson fails to teach the elements of claims not taught by Cunningham and Denny. Specifically, Edelson fails to teach use of pharmaceutical computer data to obtain a complete prescriptive history of a purchaser, and further fails to teach use of the complete prescriptive history to generate patterns, which flag prescriptive drug abuse. Edelson instead describes obtaining discrete, individual items of information for the purpose of making decisions regarding which drugs to prescribe, and does not teach or suggest obtaining a complete prescriptive history of a purchaser for purposes of flagging and preventing prescriptive drug abuse.

Denny describes a prescription verification system for tracking prescription information and communicating this information. Edelson et al. describes a prescription creation system. There exists no basis to combine Cunningham, Denny and Edelson et al. There is no basis to combine Cunningham with a prescription creation system and a prescription verification system. The combination of Cunningham in association with

creating a prescription system and verifying a prescription system is not what the present invention teaches.

Cunningham is stated as not being limited to trial products. However, Cunningham clearly distinguishes that limitations restrict its use. Particularly, Cunningham states:

It is further contemplated that the present invention can be used with not just trial products, but also actual prescribed pharmaceuticals that are past the trial stage. ... *However, this approach requires a substantial inventory of product media at the prescriber's disposal.* [Col. 3, line 54-Col. 4, line 3, emphasis added].

Cunningham teaches away from the method claimed. Specifically, Cunningham states that "in order to help combat prescription *fraud*, new systems must be developed that allow prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Col. 2, lines 55-59 of Cunningham). Thus, new systems are required to do what the claims of the present application define.

The affidavit from the inventors, Messrs. Anon and Bornfreund, explains why the cited references are not combinable.

The differences between the prior art and the present invention provide an additional secondary consideration of the nonobviousness of the invention. Cunningham tracks the efficacy of a product or clinical trial using media, and Denny describes a prescription verification system, and Edelson et al. describes a prescription creation system. Were the claimed invention to be practiced using the methodology defined by Cunningham and/or Denny and/or Edelson, the claimed invention would be inoperable for its intended purpose to prevent prescription drug abuse. Affidavit, p.4, ¶1.

The numerous secondary considerations cited in the attached affidavit of Messrs. Anon and Bornfreund illustrate the uniqueness and nonobviousness of the claimed invention.

A long felt need exists for a method for tracking prescriptive medication, to address and control prescription drug abuse and other related errors. This need has not

been met, and could not be met, by existing systems such as those found in Cunningham, Denny and Edelson et al. See, Affidavit, p.1, ¶1 through p.2, ¶2.

A further secondary consideration that weighs in favor of nonobviousness of the claimed invention is the references known to those skilled in the art, Cunningham, Denny and Edelson et al., without such individuals recognizing the significance of the claimed invention. For example, the use of tracking clinical trials and tracking payment for prescription drugs is known, but use of a prescription history for preventing prescription drug abuse is unique and nonobvious in light of these teachings. The prior art teachings did not disclose enough to make those skilled in the art aware of the claimed method. *Id.*

The complete failure of established competitors in a highly competitive market to create the present invention, despite the incentive to do so, further indicates the nonobviousness of the claimed invention. The claimed invention is a significant advancement in the art that enhances the determination of a problem that may exist intentionally or unintentionally. This effective determination is critical, the claimed invention solving a problem that a competitive market has previously failed to solve. See, Affidavit, p. 2, ¶¶ 3-4.

The claimed invention provides significant benefits not realized previously by known methodologies by defining a prescription history and speeding the awareness of and prevention of prescription drug abuse. See, Affidavit, p. 1, ¶4.

The cited references themselves illustrate the nonobviousness of the claimed method. The results obtained by the claimed invention are new and unexpected, and are suggested nowhere in the prior art. The cited references are silent concerning creation of a complete prescriptive history and using this history to prevent prescription drug abuse. See, Affidavit, p. 4, ¶1.

A further secondary consideration of nonobviousness of the present invention is the knowledge used by those skilled in the art without such individuals recognizing the significance of the claimed invention. For example, the use of tracking clinical trials and tracking payment for prescription drugs is known, but use of a prescription history for preventing prescription drug abuse is unique and nonobvious in light of these teachings. See, Affidavit, p. 4, ¶2.

Additionally, the failure of established competitors in a highly competitive market to create the present invention, despite the huge social and economic incentives to do so, further indicates the nonobviousness of the claimed invention. The claimed invention is a significant advancement in the art that enhances the determination of a problem that may exist intentionally or unintentionally. This effective determination is critical, where the claimed invention solves a problem that a competitive market has previously failed to solve, or even recognize a solution. See, Affidavit, p. 4, ¶3.

Further, the present invention provides benefits not realized previously by known methodologies by quickly defining a prescription history and speeding the awareness of and prevention of prescription drug abuse. See, Affidavit, p. 4, ¶4.

The results obtained by the present invention are new and unexpected, and are suggested nowhere in the prior art. The cited references are silent concerning the creation of a complete prescription history and using this history to prevent prescription drug abuse. See, Affidavit, p. 4, ¶5.

Finally, the evaluation of the present invention as a whole, considering the claimed structure and/or methodology, as well as its properties and the problems solved, reveals a unique, nonobvious method. The prior art teaches away from the claimed invention, failing to describe obtaining a complete prescriptive history for preventing prescription drug abuse.

The evaluation of the claimed invention as a whole, considering the claimed structure and/or methodology, as well as its properties and the problem solved, reveals a unique, nonobvious method. The prior art teaches away from the claimed invention, failing to describe obtaining a complete prescriptive history for preventing prescription drug abuse.

### **Conclusion**

In light of the above discussion, Applicant respectfully submits that the application now stands in *prima facie* condition for allowance and courteously requests that this application be advanced to issue. The Applicant is of the opinion that no fees are

required. However, if fees are required, the Commissioner is hereby respectfully authorized to deduct such fees from Deposit Account Number 13-2166.

The Examiner is respectfully invited to call the Applicant's representative at 713-355-4200, to discuss any matters that may arise, where such discussion may resolve such matters and place this application in condition for allowance.

Respectfully Submitted,

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